

REPORT OF OPINIONS OF JOHN H. STEPHENSON, M.D.

QUALIFICATIONS

I, John H. Stephenson, M.D., an anesthesiologist and President and CEO of Physician Specialists in Anesthesia, P.C., an anesthesiology and pain management practice located in Atlanta, Georgia, and its subsidiaries, state:

I graduated from the University of North Carolina-Chapel Hill School of Medicine. I completed my internship at the University of Florida Health Science Center-Jacksonville and completed my anesthesiology residency at the University of Florida College of Medicine in Gainesville, Florida. I also received advanced training in cardiovascular anesthesia from the Texas Heart Institute and completed a fellowship in pain management at the University of Virginia Pain Management Center. I am board certified in Anesthesiology, Pain Management, and Pain Medicine.

While the opinions contained herein do not necessarily reflect the official positions or opinions of any employer, company, or organization, I am currently the President and CEO of Atlanta-based Physician Specialists in Anesthesia, P.C., Physician Pain Specialists, P.C., and Pain Specialty Center of Atlanta, P.C. I am a member of the American Society of Anesthesiologists and the American Society of Anesthesiologists Committee on Practice Management. I am the Chair of the American Society of Anesthesiologists Committee on the Anesthesia Care Team and the Georgia Society of Anesthesiologists Committee on Practice Management. I am also a delegate to the House of Delegates of the American Society of Anesthesiologists, the ASA's policymaking body.

I have been continuously licensed to practice medicine in the State of North Carolina from 1989 until the present and the State of Georgia from 1993 until the present. During the 12 months preceding September 2012 until the present, I have practiced in the specialties of anesthesiology and pain management.

Additional details regarding my education and training are contained in my curriculum vitae, a copy of which is attached.

I am familiar with the recognized standard of acceptable professional practice for anesthesiologists, pain management clinics, and ambulatory surgery centers administering epidural steroid injections ("ESI's") including, but not limited to, the years 2011 and 2012, in Nashville, Tennessee, and similar communities, and Crossville, Tennessee, and similar communities. When I refer to the standard of care in this document, I am referring to the above-referenced recognized standards of acceptable professional practice during the pertinent times of the fungal meningitis catastrophe discussed herein.

I am familiar with Nashville, Davidson County, Tennessee. Metropolitan Nashville is a region of over 1,670,890 people, making Nashville the largest metropolitan area in Tennessee. It occupies the central portion of Tennessee, and lies on the Cumberland River. Similarly, the Atlanta area, a community with which I am familiar, has a population of over 456,000 and its metropolitan region has over 5,000,000 in population, making it the largest metropolitan area in Georgia. Like Nashville, Atlanta is the capital of its state.

The business climate in Nashville is very similar to that in Atlanta. Businesses include health care management, insurance, financial services, information technology, printing, “white collar work” of every type, “blue collar” work, factories, etc. Nashville is home to the *Fortune 500* Company, HCA Holdings. Nashville is the home of State Volunteer Mutual Insurance Company which insures the majority of physicians practicing in Tennessee. Other major employers in the Nashville area include Vanderbilt University and Medical Center; Nissan North America; Saint Thomas Health Services; Randstad; and Shoney’s, Inc.

Atlanta is also home to *Fortune 500* Companies, Coca Cola; Delta; Home Depot; UPS and SunTrust, to name a few. Atlanta is also the home to major employers Equifax; Carter’s, Inc.; Gentiva; Exide Technologies; Aaron’s Inc.

Nashville has a large metropolitan airport which provides service to more than 385 daily arriving and departing flights with nonstop service to more than 55 markets in the US, Canada, Mexico, Bahamas, Jamaica, Dominican Republic and Cuba. Further, I-40, the major east/west transportation route across the United States, intersects in Nashville with Interstate 65, the major north/south interstate for the central U.S. Similarly, Atlanta is served by the Hartsfield-Jackson Atlanta International Airport that has five runways that serve more than 92 million passengers a year. Three major highways (I-75, I-85, I-20) converge near the central business district. The perimeter highway (I-285) circles the city in a 62.7 loop.

Nashville also has two medical schools: Meharry Medical College and The Vanderbilt University School of Medicine. Hospitals in Nashville, Davidson County include TriStar Centennial Medical Center (657 beds), Saint Thomas Midtown Hospital (683 beds), Metropolitan Nashville General Hospital (150 beds), TriStar Summit Medical Center (196 beds), TriStar Skyline Medical Center (385 beds), TriStar Southern Hills Medical Center (126 beds), Saint Thomas West Hospital (541 beds), Monroe Carell, Jr. Children’s Hospital at Vanderbilt (222 beds), and Vanderbilt University Medical Center (863 beds).

Medical services able to be received by patients in Nashville can equally be received by patients in Atlanta. Atlanta offers the same quality of medical services as can be obtained in Nashville. The medical communities and the medical services provided are very similar. Both cities have tertiary medical centers and children’s hospitals and each offers medical specialists in all areas of medicine. Hospitals in Atlanta include Anchor Hospital (122 beds); Atlanta Medical Center (762 beds); Children’s Healthcare of Atlanta at Egleston (575 beds); Emory University Hospital (579 beds); Emory University Hospital Midtown (511 beds); Grady Memorial Hospital (916 beds); Northside Hospital (537 beds); Piedmont Hospital (529 beds); and Emory Saint Joseph’s Hospital of Atlanta (410 beds).

#### INFORMATION REVIEWED

My statements and opinions are based on my experience, training, and education along with my review of the following:

- Documents regarding the regulatory history of New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center (“NECC”);

- Information from the United States Centers for Disease Control and Prevention (“CDC”), including the *Morbidity and Mortality Weekly Report* dated December 13, 2002, regarding certain cases of fungal meningitis caused by contaminated epidural steroids made by a compounding pharmacy;
- Information published by the United States Food and Drug Administration (“FDA”) regarding compounded drug products, compounding pharmacies, and the risks associated with compounded drugs;
- Information published by The American Society of Health System Pharmacists warning the pharmacy and medical community of the risks of using compounded drugs;
- Medical records for patients who were injected with the tainted methylprednisolone acetate at Saint Thomas Neurosurgical Center;
- Information regarding beyond use dating (“BUD”) from the FDA and USP Chapter 797: De-mystifying Beyond-Use Dating;
- Review of drug shortages in June 2012 through ASHP (American Society of Health-System Pharmacists) website;
- Information from an October 23, 2003, hearing before the United States Senate’s Committee on Health, Education, Labor, and Pensions regarding pharmacy compounding;
- Certain Federal, Tennessee, and Massachusetts pharmacy laws governing pharmacy compounding; and
- The depositions and multiple exhibits of Debra Schamberg, R.N., John Culclasure, M.D., Jeff Ebel, Scott Butler, Rebecca Climer, Michael Schatzlein, M.D., Dawn Rudolph, Terry Grinder, D.Ph., Martin Kelvas, D.Ph., and Carmen Leffler, D.Ph.

#### SUMMARY OF FACTS

The substance of the facts and opinions to which I am expected to testify are developed through review of pertinent documents and deposition testimony taken in this case. In addition, I am relying upon my education, training and experience in my specialty including, where applicable, the pertinent and relevant literature.

#### NECC History

By information contained in various reports, NECC operated what it called a compounding pharmacy in Framingham, Massachusetts. Prior to the catastrophe in the fall of 2012, NECC had a history of adverse events relating to its operations. NECC operated its business on a site shared with a garbage compacting and mattress recycling business.

By information and report, NECC was the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP"). Those complaints and investigations often focused on unsterile conditions at NECC's facilities.

In 2006, the FDA issued a Warning Letter to NECC. The FDA letter detailed multiple problems at NECC including the sale of compounded drugs without patient-specific prescriptions. In addition, the FDA's Warning Letter stated that NECC was compounding copies of commercially available drugs, selling misbranded compounded drugs, and experiencing problems with storage and sterility. That warning letter was available on the FDA's website before the events described.

#### Saint Thomas Outpatient Neurosurgical Center

Saint Thomas Outpatient Neurosurgical Center ("Saint Thomas Neurosurgical") is a facility located in Nashville, Tennessee. Saint Thomas Neurosurgical specializes in providing epidural steroid injections to patients of a neurosurgery group known as the Howell Allen Clinic.

Saint Thomas Neurosurgical is located on the 9<sup>th</sup> floor of Medical Plaza East on the Saint Thomas Hospital campus. Saint Thomas Neurosurgical's receptionist, Sheri DeZwaan, wore a name tag bearing the name "Saint Thomas Hospital" at the top. According to Michael Schatzlein, M.D., President and CEO of Saint Thomas Health, Saint Thomas Neurosurgical is a for-profit joint venture which is part of the Saint Thomas Health system. In addition, Dr. Schatzlein testified as follows:

Q. Do you -- would it surprise you to learn that patients who went to the Saint Thomas Outpatient Neurosurgical Center believed that they were receiving care from an entity that was part of the Saint Thomas Health system?

A. I guess I'd have to say, no, it wouldn't surprise me.

Saint Thomas Neurosurgical is owned jointly by Saint Thomas Network and Howell Allen Clinic. Saint Thomas Network and Howell Allen Clinic share the profits generated by Saint Thomas Neurosurgical equally. Saint Thomas Network is wholly owned by Saint Thomas Health. Dr. Schatzlein described Saint Thomas Network as a pass-through entity that does not have any employees.

In 2011 and 2012, Saint Thomas Neurosurgical performed an average of 450 to 500 epidural steroid injections each month. It performed roughly 5,000 epidural steroid injections each year.

The Medical Director of Saint Thomas Neurosurgical, John Culclasure, M.D., is paid a percentage of collections for the epidural injections that he gives, and does not receive a salary. Dr. Culclasure is paid an amount equal to sixty percent (60%) of the collections for each ESI that he performs.



Martin Kelvas, D.Ph., and Saint Thomas Hospital

Martin Kelvas, D.Ph., is the former Director of Pharmacy Services for Saint Thomas Hospital. He testified that, in early 2011, a sales representative from NECC approached him in an attempt to solicit Saint Thomas Hospital's business. NECC proposed selling compounded medications in bulk to the hospital. Based upon Dr. Kelvas' general knowledge of pharmacy laws, he did not believe NECC's proposal arrangement was appropriate or lawful.

Dr. Kelvas called the Tennessee Board of Pharmacy and talked with Terry Grinder, D.Ph. of the Tennessee Board of Pharmacy. Dr. Grinder confirmed that drugs could not be lawfully purchased from a compounding pharmacy in bulk without patient-specific prescriptions. Any drugs purchased from a compounding pharmacy must be procured pursuant to an individual prescription based upon a prescriber-patient-pharmacist relationship. Dr. Grinder explained that, in order to procure medications without individual prescriptions, the drugs must be procured from an entity with a manufacturer's license.

Dr. Grinder of the Tennessee Board of Pharmacy testified that procuring medications in bulk and without individual patient-specific prescriptions from compounding pharmacies was not lawful. Whenever healthcare providers called his office with questions about compounding pharmacies, Dr. Grinder explained that medications could only be procured from compounding pharmacies by using individual patient-specific prescriptions based upon the prescriber-patient-pharmacist relationship. Bulk purchases without prescriptions could not be made from compounding pharmacies. Bulk purchases could only be made from entities with a wholesaler, manufacturer, or distributor's license. NECC did not have such a license.

Dr. Kelvas instructed all pharmacy personnel on the non-profit side of the Saint Thomas Health system not to purchase from compounding pharmacies. However, Saint Thomas Health did not instruct anyone on the for-profit side of its organization not to buy in bulk from compounding pharmacies.

Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg were required to know and follow the law. The preparation, sale, and distribution of compounded drugs, in bulk and without individual prescriptions, is unlawful in Tennessee and Massachusetts. In order for drugs to be procured from a compounding pharmacy, patient-specific prescriptions involving the prescriber-patient-pharmacist relationship must be used. *See T.C.A. § 63-10-204(4); Mass. Gen. Law c. 94C, § 17(c); and 21 U.S.C. § 353a. See also* deposition of Terry Grinder, D.Ph.

Saint Thomas Neurosurgical Purchases Injectable Steroids in Bulk from NECC

John Culclasure, M.D. is Saint Thomas Neurosurgical's Medical Director. Debra Schamberg, R.N. is the clinic's Facilities Director. Ms. Schamberg has no pharmacy training. Dr. Culclasure and Ms. Schamberg made the decision for Saint Thomas Neurosurgical to purchase methylprednisolone acetate ("MPA") from NECC.

In late 2010, Saint Thomas Neurosurgical began purchasing MPA from Clint Pharmaceuticals, a supplier and licensed wholesaler in Nashville, Tennessee. The MPA that Saint Thomas Neurosurgical bought from Clint Pharmaceuticals did not come from a compounding pharmacy. Clint Pharmaceuticals only supplied steroids manufactured by FDA-

regulated pharmaceutical manufacturers. All of the MPA purchased by Saint Thomas Neurosurgical from Clint Pharmaceuticals was FDA approved.

In June of 2011, Saint Thomas Neurosurgical chose to stop buying FDA-approved steroids through Clint Pharmaceuticals and began buying compounded MPA from NECC. Saint Thomas Neurosurgical made that change when Clint Pharmaceuticals increased its price for MPA from \$6.49 per vial to \$8.95 per vial. E-mails sent and received by Ms. Schamberg establish that Saint Thomas Neurosurgical switched from purchasing FDA-approved steroids to purchasing compounded steroids from NECC at the time of the increase. The switch from the FDA-approved MPA from Clint to what NECC supplied saved Saint Thomas Neurosurgical \$2.46 per vial.

Dr. Culclasure testified that, if Saint Thomas Neurosurgical had run short in its supply of MPA, he would have used an alternative steroid such as triamcinolone (Kenalog - Bristol-Myers Squibb) or betamethasone (Celestone Soluspan - Merck).

According to invoices produced by Saint Thomas Neurosurgical, the clinic purchased two thousand five hundred (2,500) vials of MPA from NECC during a period of three months during the summer of 2012.

Saint Thomas Neurosurgical decided to purchase compounded MPA from NECC without doing anything to learn about compounded medications in general or NECC in particular. Dr. Culclasure and Ms. Schamberg admitted that they:

- did not do any research regarding the safety and risks of compounded medications;
- did not review FDA publications and warnings regarding the dangers of compounded drugs;
- did not review medical literature regarding the risks of pharmacy compounding;
- did not make any inquiries regarding previously reported deaths caused by compounded medications;
- did not request references from NECC;
- did not investigate NECC's regulatory history;
- did not request to review NECC's sterility testing results;
- did not attempt to identify or contact any NECC customers;
- did not attempt to verify information contained in NECC's promotional literature; and

- did not consult with a pharmacist (including their own facility pharmacist consultant) for advice about purchasing non-FDA approved compounded drugs.

Dr. Culclasure and Ms. Schamberg claim that they reviewed NECC's promotional literature before approving the purchase of MPA from NECC. That literature contained the following statement:

**G. Dispensing**

Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility.

In spite of that statement, Saint Thomas Neurosurgical proceeded with bulk purchases of MPA from NECC (frequently in 500 vial batches) without using patient-specific prescriptions, and without doing any research (internet or otherwise) on NECC before they selected NECC to be Saint Thomas Neurosurgical's preferred supplier of injectable MPA.

Saint Thomas Neurosurgical Sends Patient Lists to NECC

In early to mid-2012, an NECC representative informed Saint Thomas Neurosurgical that NECC needed to receive lists of patients with each order for MPA. NECC made that request more than six months after Saint Thomas Neurosurgical started making bulk purchases from NECC. The NECC representative explained that NECC needed patient lists in order to comply with Massachusetts Board of Pharmacy requirements.

Ms. Schamberg then told the NECC representative that she could not predict which patients would receive MPA. Therefore, Saint Thomas Neurosurgical could not provide lists that would actually correspond with patients who receive MPA. In response, the NECC representative indicated that any list of patient names would suffice. Ms. Schamberg admitted that she had never received that type of request before. However, after receiving that request, she authorized the release of patient lists to NECC. She authorized the sending of patient names, even though the lists did not correspond with patients who actually received MPA compounded by NECC.

Impact on Patients

According to Dr. Culclasure, more than a hundred (100) patients contracted fungal meningitis after receiving contaminated epidural steroid injections at Saint Thomas Neurosurgical. Thirteen (13) patients died.

**OPINIONS**

Following is a summary of testimony and opinions that I expect to provide at the trial of this case, including the basis and reasons for such testimony. All of my testimony and opinions will be offered to a reasonable degree of medical certainty.

I reserve the right to amend this disclosure in the event I am provided with any additional pertinent information or, if necessary, to rebut any opinions offered by Defendants' experts.

I will testify regarding the anatomy in the region of the human spine, including the brain stem, spinal cord, cerebrospinal fluid, nerve roots, vertebrae, intervertebral discs, associated arteries, and the size and relationship of these structures and associated spaces such as arachnoid, dura, subdura, subarachnoid, and epidural.

I will offer testimony regarding the use of ESIs in pain management practice, including relieving radicular back and neck pain, nerve root compromise, inflammation, and dural irritation and how ESIs can provide non-surgical therapeutic benefits when pain is arising from structures adjacent to the epidural space.

I will testify concerning the process by which ESIs are provided to patients, including the imaging process, placement of the needle, use of contrast, and confirmation of needle placement, etc.

I will offer testimony concerning the risks involved in ESI procedures. When ESIs are performed by a skilled, experienced doctor in an appropriate setting, with carefully screened patients and appropriate medications, the chance of significant complications from an ESI is very low. For the most part, serious complications occurring after epidural steroid injections are rare.

I will offer testimony concerning the nature, application, and physiological effects of steroids such as methylprednisolone acetate, when used in a parenteral application such as a steroid injection into the epidural space.

Steroids suppress the human immune system. This is why, for example, the product literature provided by FDA-approved manufacturers warns that persons who are on corticosteroids are more susceptible to infections than are healthy individuals and there may be decreased resistance to and inability to fight localized infection when corticosteroids are used. Corticosteroids exacerbate fungal infections.

I will explain the most common steroids used in interventional pain management procedures and the attributes and availability of each. The use of Depo-Medrol (Pfizer) in ESI applications is very common, if not the most common. Other steroids that are used in ESIs include Decadron (Merck), Kenalog (Bristol-Myers Squibb) and Celestone Soluspan (Merck). Depo-Medrol, Kenalog, and Celestone Soluspan are manufactured by FDA-approved pharmaceutical companies.

Generic versions of Depo-Medrol, Decadron, Celestone Soluspan, and Kenalog are also commercially available from laboratories regulated by the FDA. These include manufacturers such as Teva and Sandoz.

There has been substantial attention in the field of pain management relating to the sourcing of steroids for parenteral use, including ESIs.

The selection of corticosteroids used in epidural steroid injections is especially critical for numerous reasons, including:



- a) The steroid is injected into the spinal canal in extremely close proximity to the central nervous system. The dura separating the spinal cord from the epidural space is very thin. If pathogens are present in the medication, they may cause a migration through the dura into the central nervous system and the spinal cord and brain. An invasive fungal infection could easily migrate through the thin protective dura layer separating the epidural space from the spinal cord or via hematogenous (bloodstream) spread to these adjacent neurologic structures;
- b) The central nervous system is a relatively closed system, inaccessible to many antibiotics and antifungals, making treatment of infection more difficult if it were to occur;
- c) As previously discussed, the steroid is an immune system suppressant. Accordingly, the medication itself will suppress the body's natural ability to fight off invading pathogens; and the steroid exacerbates fungal infection.

Since the manufactured versions of injectable steroids are commercially available, only steroids manufactured according to FDA-approved pharmaceutical manufacturing practices and by licensed manufacturers are appropriate for general use in ESIs. It is not lawful or appropriate to sell or administer compounded copies of commercially manufactured drugs.

The standard of care required Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg to provide safe, timely and effective care to the people who came to its facility to receive an epidural steroid injection. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg violated this standard of care.

The standard of care required that Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg not needlessly endanger those who came to its facility to receive the epidural steroid injection. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg violated this standard of care.

The standard of care required Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg to act in the best interest of those who came to its facility to receive the epidural steroid injection. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg violated this standard of care.

The standard of care required Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg to take all reasonable steps necessary to ensure that the product being injected into the spine was safe. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg violated this standard of care.

The standard of care required Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg to make and keep safety of the patients the top priority. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg violated this standard of care.

The decision by Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg to purchase corticosteroids from NECC for use in ESIs violated the standard of care.

The decision by Saint Thomas Neurosurgical, Dr. Culclasure, and Ms. Schamberg to administer corticosteroids from NECC to patients of Saint Thomas Neurosurgical violated the standard of care.

Dr. Culclasure and Ms. Schamberg violated the standard of care by either failing to understand and appreciate and/or choosing to ignore the risks inherent in administering ESIs using corticosteroids purchased from a compounding pharmacy.

Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg violated the standard of care when it purchased steroids in bulk from a compounding pharmacy.

As mentioned above, Saint Thomas Neurosurgical should not have been purchasing MPA from NECC in the first place. Once this entity, through its employees and/or agents, violated the standard of care by making the decision to purchase MPA from NECC, Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg continued to violate the standard of care by failing to properly conduct due diligence before doing business with NECC, and by failing to stop doing business with NECC once it asked for a random list of patient names. Saint Thomas Neurosurgical violated the standard of care when it provided a list of patient names to NECC<sup>1</sup> without regard as to whether those patients would even receive the MPA as ordered.

Unless a special medical need existed to administer compounded steroids to a particular patient (which it did not), it was a violation of the standard of care to purchase steroids from a compounding pharmacy.

Any purported desire for a preservative-free steroid (which was not the case according to Dr. Culclasure) is an insufficient justification to purchase steroids from a compounding pharmacy, and if such a decision was made on this insufficient justification, it would be a violation of the standard of care. On adult patients, any potential neurotoxin risk associated with the small amount of preservative present in commercially manufactured steroids is insignificant and, by comparison, the significant risks of purchasing these drugs from a compounding pharmacy are great and potentially lethal, as demonstrated in the NECC case histories from around the country.

During all relevant times, there were manufactured and FDA-approved steroids commercially available for use in ESIs. Any purported concerns about shortages of manufactured steroids would be an insufficient reason to purchase steroids for ESIs from a company licensed only as a compounding pharmacy in bulk without patient specific prescriptions.

The owners of Saint Thomas Neurosurgical fell below the standard of care by failing to appropriately and properly supervise, train, and manage Dr. Culclasure and Ms. Schamberg with respect to their duties to manage and direct a facility, including procurement of appropriate and

---

<sup>1</sup> Among the names of patients Saint Thomas Neurological submitted to NECC in order to procure MPA was "Mickey Mouse."

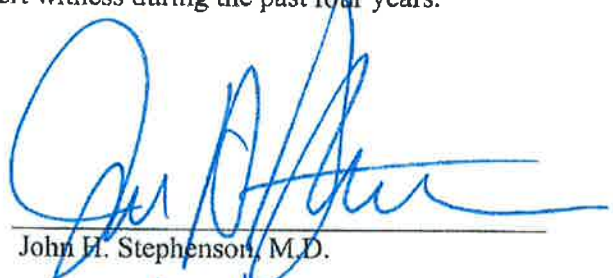
safe steroids for use in ESIs. Ms. Schamberg stated that she was not aware of the difference between a compounded pharmaceutical product and an FDA approved one. Ms. Schamberg's lack of knowledge on this issue, as well as Dr. Culclasure's and Ms. Schamberg's willingness to purchase MPA from a business that held itself out as a compounding pharmacy, in bulk, without patient specific prescriptions is a result of the failure of Saint Thomas Neurosurgical to appropriately and properly supervise, train and manage.

The owners of Saint Thomas Neurosurgical violated the standard of care by failing to have in place a proper system that would make sure the medical and facility director were aware of the laws applicable to the purchase of medications from a compounding pharmacy. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg were required to know and follow the law. The preparation, sale, and distribution of compounded drugs, in bulk and without individual prescriptions, is unlawful in Tennessee and Massachusetts. In order for drugs to be procured from a compounding pharmacy, patient-specific prescriptions involving the prescriber-patient-pharmacist relationship must be used. *See T.C.A. § 63-10-204(4); Mass. Gen. Law c. 94C, § 17(c); and 21 U.S.C. § 353a. See also deposition of Terry Grinder, D.Ph.*

It is my opinion that Saint Thomas Neurosurgical, Dr. Culclasure, Ms. Schamberg and the owners of Saint Thomas Neurosurgical failed to protect the safety of patients by failing to insure that steroids for use in ESIs were purchased from safe, appropriate sources and that such conduct violated the standard of care. Further, I am of the opinion that the above violations of the standard of care resulted in and caused injuries that otherwise would not have occurred.

#### COMPENSATION

I have been compensated in the amount of \$19,147.50 for the study and my hourly rate for testimony is \$450.00. I have not testified as an expert witness during the past four years.

  
\_\_\_\_\_  
John H. Stephenson, M.D.  
12/16/2015  
\_\_\_\_\_  
Date

**JOHN H. STEPHENSON, M.D.**

1579 Monroe Dr NE, #232 • Atlanta, GA 30324  
 Telephone: (404) 557-8226 • stephensonjh@gmail.com

**STAFF ANESTHESIOLOGIST**

Fully licensed, Board-certified, and actively practicing Anesthesiologist offering nearly 18 years of experience, advanced training, and consistently excellent performance as a tertiary care physician. Exhibits a calm, professional demeanor, demonstrating technical expertise and superior clinical competencies while practicing in an extremely challenging clinical case load. Displays an excellent bedside manner, leveraging strong communication and interpersonal skills along with genuine care, compassion, and concern for meeting patients' and surgeons' needs and providing reassurances through all phases of surgical care. Longtime mentee of Dr. Steven L. Sween, a respected figure in the fields of departmental/hospital leadership, anesthesia governance and political affairs, and practice management.

**CLINICAL & ADMINISTRATIVE EXPERTISE**

Cardiothoracic Anesthesia – Acute & Chronic Pain Management – Ultrasound-Guided Vascular Access  
 Regional Anesthesia (Ultrasound-Guided and Non-Ultrasound-Guided)  
 Practice Management – Anesthesia Billing & Compliance

**PROFESSIONAL EXPERIENCE**

**PHYSICIAN SPECIALISTS IN ANESTHESIA, P.C. – Atlanta, GA**  
**PHYSICIAN PAIN SPECIALISTS, P.C. – Atlanta, GA**  
**PAIN SPECIALTY CENTER OF ATLANTA, P.C. – Atlanta, GA**

**1996-Present**

*\$15M+ anesthesiology and pain management group widely regarded as one of the premier practices in the state of Georgia.*

**Administrative Functions:**

President / CEO / Managing Partner (2003-Present)  
 Board of Directors (2001-Present)  
 Secretary / Treasurer (2001-2003) • Chief Compliance Officer (1999-Present)  
 Section Chief – General Anesthesia (1999-2001) and Pain Management (1997-1998)

**Clinical Duties:**

Staff Anesthesiologist – St. Joseph's Hospital of Atlanta (1996-Present), Resurgens Surgical Center (1996-Present)

**Clinical Instruction Duties:**

Anesthesiologist Assistant Students in the Masters of Medical Science Program in Anesthesiology at Emory University, Atlanta, GA (1996-Present)  
 Certified Registered Nurse Anesthetist Students in the Masters of Science in Nurse Anesthesia Program at Medical College of Georgia, Augusta, GA (2004-Present)  
 Anesthesiologist Assistant Students in the Masters of Medical Science Program in Anesthesiology at Nova Southeastern University, Ft. Lauderdale, FL (2006-Present)

Joined the practice at a critical point in its 32-year history, inheriting the prior management's culture of regulatory non-compliance while addressing the fallout that stemmed from both the abrupt departure of three partners along with a federal OIG investigation.

Elected President nine years running, directing clinical/business operations, service delivery, and performance of a high-volume specialty practice delivering 27,000 patient encounters annually. Interface with the practice administrator and legal counsel regarding finance, operational, legal, and human resource matters. Collaborate with administrators in the group's partner hospital (St. Joseph's), outpatient surgery centers, as well as third-party payers to negotiate annual contracts. Control scheduling/production for 50 clinicians, coordinating effective, efficient operations and assuring premium coverage of the surgery suites.

**Organizational Leadership / Quality & Performance Improvement**

- Provided the vision, growth strategy, and leadership vital to fueling steady and sustained growth despite contending with constantly rising costs over the last decade.
- Drove a major culture change and corporate restructuring initiative that transformed the practice from a two-physician proprietorship into an equal partnership model.
- Co-authored and drove adoption by the partners of the corporate mission statement.
- Built high-performing teams of physician leaders at all levels and across all specialties of the group, including cardiac, orthopaedic, general, outpatient, pain medicine, education, and peer review/CQI.
- Led a corporate reorganization which centered on new and contemporary corporate bylaws and employment agreements. Bought midlevel providers under group employment agreements.



- Positioned the practice to achieve recognition as the first Anesthesia Quality Institute (AQI) Member Practice in Metro Atlanta and the second in the state of Georgia.
- Led and obtained industry support for a major enhancement and overhaul of the company's Quality Management (QM) system with development of a state-of-the-art clinical outcomes database.

#### **Operations & Growth**

- Recruited and successfully mentored eight new physicians into the practice. Continuously seek out high-potential talent from nationally renowned training programs.
- Spearheaded responses to RFPs published by area ambulatory surgical centers: Defined and negotiated contract terms, finalized the deals, and provided ongoing oversight for fulfillment.
- Established and maintained PSA's market standing as a leader in value, positioning it as an attractive acquisition target for anesthesiology management corporations.

#### **Marketing & Business Development**

- Authored/instituted a formal electronic survey process targeting referring surgeons and hospital/ASC administrators, securing data/feedback used in practice marketing and improving referral percentage.
- Developed the group's online presence and marketing tool through development of the corporate website ([www.psa-online.net](http://www.psa-online.net)).
- Put into place the means to measure patient satisfaction and identify areas for improvement with rollout of web- and response-card-based patient satisfaction surveys.
- Skillsets: Microsoft Excel, Powerpoint, & Word (advanced); SQL database, web Development, & HTML5 (basic)

#### **Legal & Regulatory Compliance**

- Developed the group's first formal compliance program, serving as CCO in managing the practice's Corporate Integrity Agreement and evolution into a high-values and high-trust organization.
- Conducted successful interventions for three drug/alcohol-dependent colleagues, serving as monitoring physician for the Georgia Medical Board.
- Led investigation of alleged sexual harassment involving a senior member of the practice and a facility employee, concluding the matter to all parties' satisfaction and with no legal blowback.

#### **Association Leadership and Political Relations**

- Named Chair of the American Society of Anesthesiologists Committee on the Anesthesia Care Team.
- Named Co-chair of the Georgia Society of Anesthesiologists Committee on Practice Management.
- Elected Delegate to the American Society of Anesthesiologists House of Delegates
- Forged strong relationships with U.S. Congressman John Lewis, Chief of Staff Michael Collins, and Legislative Director Michael Crowell, Esq., partnering with them in order to influence healthcare legislation.
- Led the practice to achieve 100% participation in the Political Action Committees of both the American Society of Anesthesiologists and Georgia Society of Anesthesiologists.

#### **JOSEPH L. RILEY ANESTHESIA ASSOCIATES/JLR MEDICAL - Orlando, FL**

**1994-1996**

*Prestigious, 60-physician anesthesiology, pain management, and critical care practice based at central Florida's premier hospital system, Florida Hospital/Adventist Health System; full-spectrum care spanning cardiovascular, neurological, vascular, pediatric, obstetric, pain management, and general anesthesiology.*

#### **Staff Anesthesiologist - Florida Hospital Medical Center & Florida Hospital Kissimmee**

Provided clinical expertise and services to patients at the main campus of Florida Hospital-Orlando, with primary focus in cardiothoracic anesthesiology, obstetrical anesthesiology, pediatric anesthesiology (including infants and neonates), neuroanesthesiology, and acute/chronic pain management. Went on to co-chair the Anesthesia Department at the newly launched Florida Hospital-Kissimmee.

#### **ANESTHESIA AND CRITICAL CARE ASSOCIATES OF COWETA - Newnan, GA**

**1993-1994**

*Small practice based out of Peachtree Regional Hospital (now Piedmont Newnan), a 143-bed, acute-care facility offering 24-hour emergency services, women's services and general medical/surgical services.*

#### **Staff Anesthesiologist - Peachtree Regional Hospital**

Joined this small-town practice of three anesthesiologists and five nurse anesthetists, rendering expertise in community anesthesiology, obstetric anesthesia, pediatric anesthesia, and acute/chronic pain management.

**LICENSES & BOARD CERTIFICATIONS**

**Medical Licensure:** Georgia (036018), North Carolina (34531)

**Medical Boards:** Federation of State Medical Boards Federal Licensing Examination (FLEX), 1989

**DEA:** BS3285904

**Anesthesiology:** American Board of Anesthesiology (#24129; Primary Certification 1994, Recertification 2009)

**Pain Management:** American Board of Anesthesiology Subspecialty Certification in Pain Management (#24129; Primary Certification 1996, Recertification 2007)

**Pain Medicine:** American Board of Pain Medicine (#00797)

**Perioperative Echocardiography:** National Board of Echocardiography

Examination of Special Competence in Advanced Perioperative Transesophageal Echocardiography (Advanced PTEeXAM® 2000; Recertification/RePTE 2010)

**EDUCATION**

UNIVERSITY OF VIRGINIA PAIN MANAGEMENT CENTER – Charlottesville, VA 1993  
**Fellowship in Pain Management under Dr. John Rowlingson**

TEXAS HEART INSTITUTE – Houston, TX 1991  
**Advanced Training in Cardiovascular Anesthesia under Drs. Arthur Keats and Stephen Slogoff**

UNIVERSITY OF FLORIDA COLLEGE OF MEDICINE – Gainesville, FL 1990-1993  
**Residency in Anesthesiology**

UNIVERSITY OF FLORIDA HEALTH SCIENCE CENTER – Jacksonville, FL 1989-1990  
**Internship in Internal Medicine**

UNIVERSITY OF NORTH CAROLINA – Chapel Hill, NC 1985-1989  
**Doctor of Medicine (M.D.)**

WAKE FOREST UNIVERSITY – Winston-Salem, NC 1981-1985  
**Bachelor of Arts in Chemistry**

**PROFESSIONAL MEMBERSHIPS & ACTIVITIES (current unless otherwise noted)**

American Society of Anesthesiologists (ASA)

Chair, Committee on the Anesthesia Care Team (2012-present)

Member, Committee on Practice Management (2011-present)

Political Action Committee Key Contact

Delegate to the ASA House of Delegates

Georgia Society of Anesthesiologists (GSA)

Co-Chair, Committee on Practice Management (2011-present)

Executive Committee (2011-present)

Society of Cardiovascular Anesthesiologists (SCA)

American Society of Regional Anesthesia and Pain Management (ASRAPM)

Medical Association of Georgia (MAG)

Medical Association of Atlanta (MAA)

St. Joseph's Heart and Vascular Institute / CV Partners LLC: Board of Directors (2010-2012); Operations and Quality Committee (2009-2012)

Georgia Composite Medical Board: Peer Reviewer

Georgia Society of Anesthesiologists: Political Action Committee

St. Joseph's Hospital of Atlanta: Credentials Committee, Pharmacy & Therapeutics Committee

**PUBLICATIONS**

Stephenson JH and Clark R. **Incorporating Anesthesiologist Assistants (AAs) Into Your Practice.** ASA Newsletter (Jan 2013), 77:1, 14-16.  
Field J, Rathmell JP, Stephenson JH, and Katz NP. **Neuropathic pain following cervical epidural steroid injection.** Anesthesiology (2000), 93(3):885-8

**LECTURES****Aspiration and Full-Stomach Precautions: Where Are We in 2012?**

American Academy of Anesthesiologists Assistants Annual Meeting, San Antonio TX, April 2012  
St. Joseph's Hospital Anesthesiology Grand Rounds, 2011

**Perioperative Corneal Abrasion: Causes, Prevention, and Treatment**

American Academy of Anesthesiologists Assistants Annual Meeting, San Antonio TX, April 2012  
St. Joseph's Hospital Anesthesiology Grand Rounds, 2008

**Platelet Function and Antiplatelet Therapy,** St. Joseph's Hospital Anesthesiology Grand Rounds, 2007**Geriatric Anesthesia,** St. Joseph's Hospital Anesthesiology Grand Rounds, 2006**Upper Extremity Regional Anesthesia,** St. Joseph's Hospital Anesthesiology Grand Rounds, 2004**Chemical and Biological Warfare: A Primer for the Anesthesia Professional,** St. Joseph's Hospital Anesthesiology Grand Rounds, 2002**The Internet and Anesthesia,** St. Joseph's Hospital Anesthesiology Grand Rounds, 1999**PERSONAL INFORMATION**

Birthplace: Rockingham, North Carolina  
Date of Birth: September 14, 1963  
Married to: Daniela S. Ezratty, MSN, ACNP-BC